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510(k) Summary

MAR 2 4 2003

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	Vascular Architects, Inc.
Contact Person	Phyllis Elson, Sr. Director, Regulatory Affairs 408-392-7437
Date Prepared	February 21, 2003
Name	Vascular Architects aSpire™ Covered Stent and Controlled Expansion™ Delivery System
Classification Names	Tracheal Prosthesis
Device Classification	Classification: Class II Product Code: JCT Regulation Number: 21 CFR § 878.3720
Predicate Device(s)	Vascular Architects aSpire™ Covered Stent and Controlled Expansion™ Delivery System, cleared under 510(k) K012544 on November 15, 2001
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act
Device Description	The Vascular Architects aSpire™ Covered Stent is a spiral stent made from Nickel Titanium completely covered with ePTFE. The ePTFE is formed into a tube and pulled over the stent frame and sealed at the ends so that there is no exposed metal. The Controlled Expansion™ Delivery System allows the user to position the stent and image it in place prior to release of the stent from the delivery catheter.

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Indications for Use	The Vascular Architects aSpire™ Covered Stent and Controlled Expansion™ Delivery System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms and for the treatment of benign strictures after all alternative therapies have been exhausted.
Technological Characteristics	The 15 cm Vascular Architects aSpire™ Covered Stent contains the same features and functions that the currently cleared 2.5, 5, and 10 cm long Vascular Architects aSpire™ Covered Stent. The only difference is the length of the stent. Lengthening the stent to 15 cm does not 1) affect the device's intended use, or 2) alter the device's fundamental scientific technology. No modifications have been made to the device's operating principle or mechanism of action.
Nonclinical Performance	A battery of physical tests and simulated deployments were performed to confirm that the product meets its intended performance specification.
Conclusion	The 15 cm The Vascular Architects aSpire™ Covered Stent is substantially equivalent to the legally marketed 2.5, 5, and 10 cm long Vascular Architects aSpire™ Covered Stents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2003

Ms. Phyllis Elson
Senior Director, Regulatory Affairs
Vascular Architects, Inc.
1830 Bering Drive
San Jose, California 95112-4226

Re: K030567
Trade/Device Name: aSpire™ Covered Stent and Controlled Expansion™ Delivery System
Regulation Number: 21 CFR 878.3720
Regulation Name: tracheal prosthesis
Regulatory Class: II
Product Code: JCT
Dated: February 21, 2003
Received: February 24, 2003

Dear Ms. Elson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K030567

Device Name: Vascular Architects aSpire™ Covered Stent and Controlled Expansion™ Delivery System

Indications for Use:

The Vascular Architects aSpire™ Covered Stent and Controlled Expansion™ Delivery System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms and for the treatment of benign strictures after all alternative therapies have been exhausted.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030567

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)